

What is claimed is:

1. A method for obtaining interstitial fluid for diagnostic testing comprising:
 - (a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;
 - (b) collecting the sample from the opening, wherein step (b) is enhanced by applying a vacuum to the selected area of the skin.
2. A method for obtaining biological fluid for diagnostic testing comprising:
 - (a) forming an opening in an area of skin suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the fluid;
 - (b) extracting the sample from the opening, wherein at least one of positive and negative pressure is employed in order to enhance the extraction of the sample.
3. The method of claim 2 wherein the biological fluid comprises blood.
4. The method of claim 2 wherein the biological fluid comprises interstitial fluid.
5. A multi-layer integrated device comprising:
 - (a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;
 - (b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid; and
 - (c) a substrate layer that is capable of being in contact with a processing circuit, wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and facilitates the movement of the biological fluid to the

sensor (b); and further wherein said substrate layer (c) has at least one opening therein.

6. A multi-layer integrated device comprising:

- (a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;
- (b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;
- (c) a substrate layer that is capable of being in contact with a processing circuit, and
- (d) a bottom layer; wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and wherein said substrate layer (c) has at least one opening therein.

7. An integrated device comprising:

- (a) a pad capable of receiving and transporting a biological sample containing an analyte;
- (b) a detector for detecting the presence and/or quantitating the concentration of analyte in the sample, said mechanism capable of being in contact with a display for illustrating results of the detector; and
- (c) a strap or adhesive tape for holding the pad to an area of skin surface, wherein the integrated device contains at least one opening suitable to allow the biological sample to contact the pad.

8. The integrated device of claim 7 wherein the pad contains a surfactant to facilitate transport of the sample across the pad.

9. An integrated device for removing and testing a biological sample from the skin comprising;

- (a) a lower section having at least one opening therein;

(b) a pad capable of collecting and transporting a biological sample containing an analyte; and

(c) a detector for determining the presence and/or quantity of the analyte, said detector capable of being in contact with a display for the results of the detector.

10. The integrated device of claim 9 wherein the pad contains a surfactant to facilitate transport of the sample across the pad.

11. An integrated fluid harvesting and analysis device, comprising:

(a) a first layer having a porating element disposed thereon, the porating element forming at least one opening in the tissue;

(b) a sensor positioned in fluid communication with the at least one opening in the tissue, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid.

12. The device of claim 11, and further comprising a second layer overlying the first layer, the sensor being positioned between the first layer and the second layer.

13. The device of claim 11, wherein the porating element is a heat conducting element that is heatable such that the temperature of tissue-bound water and other vaporizable substances in a selected area of the surface of the tissue proximate the heat conducting element is elevated above the vaporization point of water and other vaporizable substances thereby removing the surface of the tissue in said selected area.

14. The device of claim 13, wherein the porating element comprises a quantity of photothermal material that is responsive to application of optical energy to heat up

and conduct heat to the surface of the tissue for forming at least one opening therein.

15. The device of claim 14, wherein said second layer comprises a portion which is transparent to optical energy.

16. The device of claim 11, wherein the porating element comprises at least one mechanical puncturing member protruding from a bottom surface of the first layer.

17. The device of claim 11, wherein the sensor comprises an electrochemical biosensor which is responsive to a level of glucose in interstitial fluid.

18. The device of claim 11, wherein the sensor comprises a colorimetric sensor that provides an indication of glucose level in interstitial fluid.

19. The device of claim 11, wherein the sensor comprises an assay pad having a reactive area that is positioned with respect to the at least one opening in the first layer tissue to absorb biological fluid collected therethrough.

20. The device of claim 19, and further comprising a mesh layer overlying the assay pad to transport biological fluid onto and across the reactive area of the assay pad.

21. The device of claim 20, wherein the mesh layer is treated with a surfactant substance to enhance the transport of biological fluid onto and across the reactive area of the assay pad.

22. The device of claim 19, wherein the sensor comprises an anode, a cathode, a reference electrode and a sense electrode, each of which is electrically coupled to the reactive area of the assay pad.

23. The device of claim 19, wherein the assay pad of the sensor is disposed along at least portion of an inner wall that extends perpendicular to a surface of the first layer.

24. The device of claim 11, and further comprising an sonic transducers formed of a compliant sonic transmissive material positioned above the layer to deliver sonic energy to the tissue surrounding a location of the tissue where the at least one opening is to be formed.

25. The device of claim 24, wherein the sonic transducer is formed of a compliant silicone material.

26. The device of claim 24, and comprising at least two sonic transducers positioned on opposite sides of the sensor.

27. The device of claim 11, and further comprising a sonic transducer formed of a compliant sonic transmissive material positioned above the layer to deliver sonic energy to the tissue surrounding a location of the tissue where the at least one opening is to be formed.

28. The device of claim 11, wherein the porating element comprises at least one electrically energized heat conducting element.

29. The device of claim 28, and further comprising at least two conductors embedded in the tissue-contacting layer and the at least one electrically energized heat

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conducting element being connected to the conductors for supplying electric current to the at least one electrically heatable element.

30. In combination, the integrated device of claim 11, and a mechanical element having a small opening therein and capable or receiving the integrated device such that the probe is aligned with the small opening, the mechanical element responsive to downward force thereon to cause the surface of the tissue to bulge into the small opening.

31. In combination, the integrated device of claim 11, and sealing means for pneumatically sealing the integrated device to the surface of the tissue and forming a sealed chamber, and means coupled to the sealing means for supplying negative pressure to the sealed chamber.

32. The combination of claim 31, and further comprising a sealed electrical connection to the sensor and/or probe via the sealing means.

33. The device of claim 12, and further comprising a fluid management chamber in a region of the integrated device between the first layer and the second layer, wherein surfaces in the fluid management chamber are treated with a chemical substance so as to facilitate the flow of biological fluid to the sensor.

34. The device of claim 33, wherein surface portions of the layer are coated with hydrophobic substances.

35. The device of claim 11, and further comprising a sense electrode coupled to the sensor to facilitate determination that the sensor is sufficiently wetted with biological fluid.

36. The device of claim 11, and further comprising means for coupling sonic energy through the device to the tissue.

37. The device of claim 36, and further comprising control means for controlling parameters of the sonic energy so that the sonic energy is adjusted to optimize each stage of a harvesting and analysis process.

38. An integrated fluid harvesting and analysis device, comprising:

- (a) a first layer for positioning in contact with tissue and through which poration of tissue is achieved such that at least one opening is formed in the first layer and at least one opening is formed in the tissue;
- (b) a sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid.

39. The device of claim 38, and further comprising a second layer overlying the first layer, the sensor being positioned between the first layer and the second layer.

40. A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:

- (a) placing a layer in contact with a surface of tissue;
- (b) forming at least one hole in the tissue;
- (c) collecting biological fluid from the tissue through at least one opening in the layer; and
- (d) wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic of the biological fluid.

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41. The method of claim 40, wherein the step of forming the at least one opening in the layer and the at least opening in the tissue comprises applying optical energy to a photothermal material on the layer that is contact with the tissue to thermally ablate the tissue and form the at least one opening therein.

42. The method of claim 40, wherein the step of forming the at least one opening in the layer and the at least one opening in the tissue comprises applying electrical energy to a heat conducting element on the layer that is in contact with the tissue to thermally ablate the tissue and form the at least one opening therein.

43. The method of claim 40, wherein the step of forming a hole in the tissue comprises forming at least one hole through the layer and into the tissue, wherein biological fluid from the tissue is collected through the hole in the layer.

44. The method of claim 40, wherein the step of forming a hole in the tissue comprises forming at least one hole in the tissue adjacent to the layer.

45. The method of claim 40, wherein the step of measuring comprises measuring an electrical characteristic of the sensor.

46. The method of claim 40, wherein the step of measuring comprises measuring a characteristic of light reflected from the sensor.

47. The method of claim 40, and further comprising the step of applying positive pressure to the layer so as to induce flow of biological fluid through an inlet port.

48. The method of claim 40, and further comprising the step of creating a negative pressure above the layer so as to draw biological fluid into the inlet port.

49. The method of claim 48, and further comprising the step of forming a sealed chamber over the layer and the sensor.

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